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Title: **Infusion Bag with a Port System**

Summary: An infusion bag with a port system therein characterized, in that the injection outlet port is thin walled and flexible and approaches an elliptical cross-section in the welding area, which for welding in the membrane can be pressed together to be flat.

Description

A Port System for an Infusion Bag and the Manufacture thereof

The occasion of the present port system is a novel part discovered for the simple and secure manufacture and the use of infusion bags with advantageous, liquid medicines and medicinal products.

Infusion bags are, among other items, being applied more and more for sterile medicinal liquids. These infusion bags require a port system, by means of which a transmission of the infusion material to the patients is made possible. Additionally, the addition of, for example, medicaments, becomes possible. The port system influences then, decisively the manufacture of the infusion bags and the mode of their filling.

Customarily such infusion bags are provided with ports, which are connected by means of a tube to the infusion bag. This requires many labor steps in the manufacture, along with many individual components and critical injection connections. An advanced form presents injection molding connections, which are directly welded into the membrane of the infusion bags. These are, in the area of the welding point, designed as "boats" and have to be made rugged in order to produce the necessary back pressure to the welding tools. Such a device has been achieved with a corresponding stable spanning construction. What is disadvantageous, among other things, are the large consumption of material of the parts and the transition of the soft membrane to friable boats, which can lead to membrane perforations and do not provide resistance to mechanical loadings. The transparency of the parts is limited because of the necessary thickness of the walls. The

filling procedure requires an opening in the port. Since, in a rigid port, after the filling has taken place, the filling tube to be welded is very difficult to work and mostly the removal opening is employed for the filling, and then closed with the customary corks, or caps. This requires additional labor steps in the manufacture and reduces the size of the ports. For example membrane separations between the product and the rubber are not possible. Also, sterile coverings of the removal points can be scarcely realized.

Thus the invention takes on the purpose of creating a port, which is simple and secure to make, to work with, and to apply in action. The invented port is to fit well into the characteristic features of the infusion bags and be economical in its manufacture.

The said purpose is achieved as follows:

For one infusion bag (1) a novel port (2) has been discovered, which, by possessing a high degree of shape flexibility and an elliptic welding geometry fulfills all requirements. The port body (3) is of one-piece and injection molded, possesses a small wall thickness and is made from a sufficiently flexible material. At the infusion bag site, the port shows an elliptical cross-section (4). This cross-section, when used in connection with port flexibility gained through the light wall thicknesses and the material elasticity, enables the easy compression of the welding surfaces (5), whereby a stable, flat welding geometry (6) is made available. By means of this stabilization, a welding with the membrane is simple, safe and as quick as possible. Counter pins or a shape-stabilizing part construction are no longer necessary. The welding surfaces can be smooth or be provided with welding profiles. An infusion bag placement one welding step for the circumference and the port is thereby possible.

In the port body (3) is a separate filling opening (7), which, following the filling procedure is closed, preferably by welding (8) and a subsequent cut-off near to the said port is possible. In this way, the filling tube is not disturbed during a later application.

The removal site can be freely formed, since it is not employed as a filling opening. Advantageously, this port is closed with a one-piece, membrane (9), molded along with the port body. Thereupon is to be found a septum (10) made of an elastomer. Advantageously, this is made from a type TPE-Material, which can be directly injection molded. Thereby, the achievement is, the making of a simple, safe and sterile connection.

The infusion tube points, namely, can be sterilely closed until a time of use by appropriate covers (11), such a caps, or coil membranes.

The infusion bag (1) with a port system (2) can be sterilized at a temperature of 115°C, which is the minimum allowable.

By means of the small overall length of the port system, a compact infusion bag is achieved, which, for example, allows itself to be packed at small packing costs (cartons, wrapping membrane, etc.). Also the danger of shipping damage is reduced. Infusion bags with this port are likewise adaptable for use without outer membranes, since the formulation, construction and the sterility requires no further outer protection. The flexible port increases the durability of the welding and thereby the safety by its resilience upon pressure peaks.

The ports can be prefabbed in the factory, complete and economically, so that the manufacturing costs require only a few work-up steps, which increases the reliability and the product quality thereof.

One embodiment form is shown in Drawing 1.

Claims

Claimed is:

1. An infusion bag with a port system, therein characterized, in that the injection molded port is thin walled, and flexible and possesses an approximate elliptical cross-section in the welding area, which can be collapsed flat for the welding in the membrane.
2. A port system in accord with claim 1, therein characterized, in that the port contains a separate filling opening.
3. A port system in accord with claim 1 therein characterized, in that the filling opening is support shaped, flexible and can be welded.
4. A port system in accord with claim 1, therein characterized, in that the port contains an injection molded membrane for its closure.
5. A port system in accord with claim 1, therein characterized, in that the port possesses an elastomer for the sealing and the retention of tapping pins.

6. A port system in accord with claim 1, therein characterized in that the elastomer is a type TPE plastic.
7. A port system in accord with claim 1, therein characterized that the TPE plastic is directly injected into the port.
8. A port system in accord with claim 1, therein characterized that the tapping position is covered in a sterile manner.
9. An infusion bag with a port system, in accord with claim 1, therein characterized, in that it can be sterilized at least at 115°C.
10. An infusion bag with a port system, in accord with claim 1, therein characterized, in that the circumference of the infusion bag and the port can be welded together in one minute.

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